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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,295

06/09/2005

Ta-Yuan Chang

DC-0315

1139

26259

7590

06/15/2007

LICATA & TYRRELL P.C.

66 E. MAIN STREET

MARLTON, NJ 08053

EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

06/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,295

Applicant(s)

CHANG ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/09/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III, claims 8 - 11 in the reply filed on March 29, 2007 is acknowledged. The traversal is on the ground(s) that the groups have the same special technical feature and therefore have the same search and no search burden. This is not found persuasive because while the searches for the groups may overlap, an overlapping search is not a coextensive search. Thus a reference that anticipates one group may not anticipate or even make obvious the invention of another group. Furthermore, as evidenced by the cited references and rejections below, the groups fail to contain a special technical feature which contributes over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1 – 11 are pending; claims 1 – 7 are withdrawn as being drawn to non-elected subject matter; claims 8 – 11 have been considered on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for preventing diseases or disorders associated with over accumulation of cholesterol. "Prevention" provides the expectation that the disorder/condition does not occur in response to a challenge or initiating event. While there is no requirement that prevention must be absolute in all cases, there is a reasonable expectation that some element of prevention can be shown. The standard for such is extremely high, and it is expected that the showing will be actual rather than implied, prophetic, or with a model. The standard of enablement is higher for such inventions because effective preventions of disease conditions are relatively rare and may even be unbelievable in the absence of strong supporting evidence.

The instant specification fails to teach one in the art how to practice the claimed method of preventing disease or disorders associated with over accumulation of cholesterol. The specification is absent working examples of how the invention might prevent the instant diseases, it fails to teach any compound that would be identified in such a method, and does not provide any guidance as to how much such a compound would be required to prevent the diseases/disorders. As such, a person of ordinary skill in the art would not know immediately recognize how to administer a compound to prevent the instant disorders. Moreover, it would place an undue burden of experimentation to find suitable disorders that can be prevented and

what compounds can be used to prevent those disorders, in addition to how much and often such a compound should be administered.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8 – 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 – 11 are drawn to methods for inhibiting over accumulation of cholesterol in cells and methods for treating disorders related thereto, however are rendered vague and indefinite because the claims depend on withdrawn claims.

The claims are further indefinite because the claims fail to include compounds by which the methods can be achieved.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 8 – 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Deboeck et al. (US 5545628).

Applicant claims methods for inhibiting over accumulation of cholesterol in cells, the method comprising administering to the cell, compounds identified to modulate cholesterol accumulation by a particular method. Applicant additionally claims a method for treating or preventing diseases/disorders associated with cholesterol accumulation, the method comprising administering compounds identified to modulate cholesterol accumulation by a particular method.

Deboeck teaches methods for treating hyperlipidemia or hypercholesterolemia (over accumulation of cholesterol) by administering fenofibrate to a mammal (to include cells thereof) (abstract, claims). Although the reference does not teach the compound can be identified by the disclosed method, the compound is clearly identified as one which modulates, inhibits and reduces over accumulation of cholesterol (col.1 line 13-25). Thus, the reference compound must also be identifiable via the claimed method.

Therefore the reference anticipates the claimed subject matter.

8. Claims 8 – 11 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Chang (WO 02/068681).

Applicant claims methods for inhibiting over accumulation of cholesterol in cells, the method comprising administering to the cell, compounds identified to modulate cholesterol

accumulation by a particular method. Applicant additionally claims a method for treating or preventing diseases/disorders associated with cholesterol accumulation, the method comprising administering compounds identified to modulate cholesterol accumulation by a particular method.

Chang teaches methods for inhibiting over accumulation of cholesterol and methods for treating/preventing diseases/disorders relating to over accumulation of cholesterol, the methods comprising administering compounds identified as cholesterol inhibitors (claims). Although the reference does not teach the compound can be identified by the exact methods as claimed, the compounds are clearly identified as those which modulate, inhibit and reduce over accumulation of cholesterol (claims). Thus, the reference compound must also be identifiable via the claimed method.

Therefore the reference anticipates the claimed subject matter.

9. Claims 8 – 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang US 2004/0115613).

Applicant claims methods for inhibiting over accumulation of cholesterol in cells, the method comprising administering to the cell, compounds identified to modulate cholesterol accumulation by a particular method. Applicant additionally claims a method for treating or preventing diseases/disorders associated with cholesterol accumulation, the method comprising administering compounds identified to modulate cholesterol accumulation by a particular method.

Chang teaches methods for inhibiting over accumulation of cholesterol and methods for treating/preventing diseases/disorders relating to over accumulation of cholesterol, the methods comprising administering compounds identified as cholesterol inhibitors (claims). Although the reference does not teach the compound can be identified by the exact methods as claimed, the compounds are clearly identified as those which modulate, inhibit and reduce over accumulation of cholesterol (claims). Thus, the reference compound must also be identifiable via the claimed method.

Therefore the reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

June 8, 2007